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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,248

09/22/2006

Elliott P. Dawson

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,248	Applicant(s) DAWSON ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 0209.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 25-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 07/21/2009 has been considered and entered for the record.

PRELIMINARY REMARKS

2. Claims 24-48 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.
3. Applicant's request for a rejoinder of the method claims will be considered in the event that there is allowable subject matter.
4. The amendments to claims 1, 5-9, 17, 20 and 21 has been noted by the examiner. As such, applicant's amendment overcomes the 35 USC 112, second paragraph rejection in paragraph 5 of the Office Action mailed on 04/21/2009.
5. Applicant's amendment overcomes the 35 USC 102(b) and 35 USC 103(a) rejections in the Office Action mailed on 04/21/2009.
6. The rejections of claims 15 and 24 were inadvertently left out of the previous action and will be included in this action.
7. Claims 1-24 are pending further examination upon the merits.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 1-14, 16, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. (US 5,585,275) in view of Ullman et al. (US 4,857,453).

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12. Hudson discloses a device for peptide synthesis and screening where this device is fully capable of collecting and preserving nucleic acids that includes for claim 1 a single substrate (substrate 5) or support that has a top, opposing bottom and a lateral edge surrounding the surface (Fig. 1). This substrate also includes an array of holes (holes 11) or sample zones that are used to hold a sample disc (disc 50). Moreover, these holes form a recess or well within the substrate (substrate 5) that includes a portion (hole 53) that allows the disc to be removed for further processing (col. 5 lines 10-14). As can be seen from Figure 8a, the disc (disc 50) is retained within the hole or recess of the support. Finally, the absorbent material used by Hudson bind a target molecule to the matrix of the absorbent material or wink and these porous members are punched out into a vial for determining the specificity of binding of a target molecule to a label (col. 18 lines 13-18).

13. The applied reference of Hudson differs from claim 1 in that the disc (disc 50) does not require a stabilizer or buffer to be incorporated within the absorbent material.

14. Ullman discloses an immunoassay device that includes a liquid absorbing zone that uses ancillary materials such as buffers and stabilizers in order to maintain the condition of the collected sample within a hydrophilic absorbent material. For claim 1, Ullman discloses using various buffers such as tris or barbital to maintain the pH the desired pH of the solution (col. 14 lines 60-62). Ullman shows that using a buffer such as tris to maintain a significant site binding affinity for an assay or sample collection was a conventional use of a buffer at the time of the instant application. Therefore, it would have been obvious to one of ordinary skill in the art to employ the buffer as suggested

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by Ullman within the absorbent material of Hudson in order to obtain the predictable result of maintaining the collected sample.

15. For claims 2 and 3, Hudson discloses that the substrate is made of a polyolefin polymer (col. 6 lines 58-60) where polypropylene is classified as polyolefin polymer and is being interpreted as the hydrophobic substrate of the instant application.

16. For claim 4, the substrate (substrate 5) has a rectangular shape (Fig. 1) and for claims 5-7, Hudson discloses that the spaced array can number anywhere from a 4x4 array (16 wells) to a 400x400 array (1600 wells; col. 6 lines 57-64). With regards to claims 8 and 10, the holes are circular in shape and are identical to each other (Fig. 1).

17. Regarding claim 9, Hudson does not disclose that holes or capture zones have different shapes. However, the use of a differently shaped wells is an engineering design choice that would be obvious to one of ordinary skill in the art absent any alleged unexpected results or persuasive evidence that the new configuration operates differently from the prior art.

18. For claim 11, the combined composition of Hudson, Yokoyama and Ullman is being interpreted as being in a solid state and for claim 12 the matrix material used to hold the DNA sample can be made from cellulose such as cotton which is a fibrous material (col. 11 lines 25-30 & 34-36). For claims 13 and 14, the cotton matrix has the intrinsic property of being hydrophilic and the disc/matrix is composed of one material.

19. With regards to claim 16, Hudson also discloses that the disc or absorbent material can be made from cellulose and from inorganic materials such as silica (col. 11 lines 36-37).

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20. For claim 22, the holes of Hudson would appear as depressions when viewed from above.

21. Hudson differs from claim 23 in that a handle is required for claim 23.

22. For claim 23, Ullman discloses a housing (housing 12) that is fully capable of functioning as a handle. Therefore, it would have been obvious for one of ordinary skill in the art to employ the handle as suggested by Ullman with the sample device of Hudson in order to obtain the predictable result of positioning the device in order to collect a sample.

23. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. (US 5,585,275) in views of Ullman et al. (US 4,857,453) as applied above and in further views of Yokoyama et al. (US 2004/0147854 A1) and Fukunishi et al. (US 6,084,005).

24. Claim 17 differs from Hudson and Ullman in that the stabilizer required is from the group consisting of dodecyl sulfate, a lithium salt, an anionic salt or cetyl pyridinium hydrochloride.

25. With regards to claim 17, Yokoyama discloses using cetylpyridinium chloride ([0038]) as the bactericidal ingredient, but differs from claim 17 regarding the use of the hydrochloride. While the bactericidal ingredient used by Yokoyama is for the preservation of D-glucose and not nucleic acids, the collection device of Yokoyama is fully capable of preserving nucleic acids and further demonstrates that preserving a biological sample from collection to testing was a known problem at the time of the

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instant application which is solved by the analogous composition of Yokoyama.

Therefore, it would have been obvious for one of ordinary skill in the art to employ the bactericide suggested by Yokoyama within the collection device of Hudson and Ullman in order to obtain the predictable result of preserving the collected sample.

26. However, the combined teachings of Hudson, Ullman and Yokoyama differ from claim 17 with regards to the cetylpyridinium hydrochloride used to preserve the collected sample.

27. Fukunishi discloses using cetylpyridinium hydrochloride as a microbiocide within an antimicrobial carrier-detector composition (col. 6 lines 1-3). Furthermore, the uses of both compounds, cetylpyridinium chloride of Yokoyama and cetylpyridinium hydrochloride of Fukunishi, are known within the art and would have been known to one of ordinary skill in the art at the time of the instant application. Therefore, it would have been obvious for one of ordinary skill in the art to employ the cetylpyridinium hydrochloride biocide of Fukunishi within the bactericide of Hudson, Ullman and Yokoyama in order to obtain the predictable result of sterilizing bacteria that might affect the results of the collected sample.

28. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. (US 5,585,275) in view of Ullman et al. (US 4,857,453) as applied above and in further view of Zhang-Keck and Stallcup (*Journal of Biological Chemistry*, vol. 263, No. 7 pp3514) (will be referred to as Zhang-Keck).

29. Hudson and Ullman differ from the stabilizers and antioxidants of claims 18-21.

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30. Zhang-Keck discloses an assay that includes optimized reaction conditions and specific inhibitors for the initiation of transcription by RNA polymerase that for claims 18-21, that includes using a composition with Vanadyl ribonucleoside complex, Na₂ EDTA, bovine serum albumin and Tris/hydrochloride (page 3514, Experimental procedures) where the vanadyl complex is being interpreted as a vanadyl complex since it appears that both are alternative spellings for the same compound. While Zhang-Keck do not specifically state that the buffer is only Tris, however, Tris is a well known buffer in the art that one of ordinary skill in the art could easily substitute in place of the buffer used by Zhang-Keck. Further, it would be obvious to one of ordinary skill in the art to employ the composition of Zhang-Keck within the device of Hudson and Ullman in order to maintain the viability of the saliva sample obtained by the device. The suggestion for using this composition at the time of the instant application would have been in order to have the efficient removal of cyto-plasmic debris in order to prevent severe degradation of the RNA products of the reaction (page 3516, *Effect of Ribonuclease Inhibitors*).

31. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. (US 5,585,275) in view of Ullman et al. (US 4,857,453) as applied above and in further view of Dores et al. (US 2002/0039796 A1).

32. The combined teachings of Hudson and Ullman differ from claim 15 regarding the use of more than one absorbent material.

33. Dores discloses a device for cytology slide preparation that includes using an inert hydrophilic absorbent as part of the slide. For claim 15, Dores discloses using

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materials for the absorbent such as 100% cotton fiber, polyvinyl acetal foam or cellulose fiber ([0035]). As far as using multiple materials for the absorbent material, Does further discloses that a combination of materials can be used as the absorbent material and that this is known within the art ([0035]). Therefore, it would be obvious for one of ordinary skill in the art to employ the absorbent materials as suggested by Does within Hudson and Ullman in order to obtain the predictable result of retaining nucleic acid within a sampling device.

34. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. (US 5,585,275) in view of Ullman et al. (US 4,857,453) as applied above and in further view of Johnson (US 4,192,330).

35. Claim 24 differs from the combined teachings of Hudson and Ullman in that the handle is a loop.

36. Johnson discloses a holder for dental floss that for claim 24 includes using a handle (handle 24) that is in the shape of a loop (col. 5 lines 37-39; Fig. 1). The shape of the handle of Johnson is used to form a tension spring that is used to spread apart two arms that hold dental floss. In this case, Johnson shows that the use of a loop as a handle was known at the time of the instant application and would have been an obvious design choice for the handle. Therefore, it would have been obvious for one of ordinary skill in the art to employ the handle suggested by Johnson with the sample device of Hudson and Ullman in order to obtain the predictable result of providing a surface for handling the saliva sampling device.

Response to Arguments

37. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

38. The new grounds of rejection are in view of Hudson which discloses a single support or substrate for holding a plurality of sample wells.

Conclusion

39. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1797

/William H. Beisner/
Primary Examiner, Art Unit 1797